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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,355	08/01/2005	Ira B. Black	UMD-0103	2346
<div>46046 7590 09/19/2008 LICATA &amp; TYRRELL P.C. 66 EAST MAIN STREET MARLTON, NJ 08053</div>				
<div>EXAMINER HAYES, ROBERT CLINTON</div>				
<div>ART UNIT 1649</div>		<div>PAPER NUMBER</div>		
<div>NOTIFICATION DATE 09/19/2008</div>		<div>DELIVERY MODE ELECTRONIC</div>		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

### Office Action Summary

**Application No.**

10/533,355

**Applicant(s)**

BLACK, IRA B.

**Examiner**

Robert C. Hayes, Ph.D.

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 May 2008.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 is/are pending in the application.  
4a) Of the above claim(s) 1, 2 and 4 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 3 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☒ Claim(s) 1-4 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO/ISD)  
Paper No(s)/Mail Date 8/105,9/05,8/1407  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group II (claim 3) in the reply filed on 1/29/08 and 5/23/08 is acknowledged. The traversal is on the ground(s) that "Applicant respectively disagrees with the Examiner's assertion that PCT Rule 13 does not provide for multiple products or methods within a single application", and that "Rule 13.1 shall be fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features". In contrast to Applicants' assertions, no "*special*" technical feature exists as clearly made of record in the Lack of Unity requirement in Paper Number 20080107, because Barde et al (US Patent 5,180, 820) teach a method of treating neural tissue with BDNF, and therefore, no "*special*" technical feature exists under PCT Rule 13.2, because it does not define a contribution over the prior art (i.e., as it relates to claim 1). Claim 3 is directed to different screening methods *not requiring BDNF* (unlike claim 1), in which no steps are recited for measuring synaptic growth or plasticity, except for detecting activation of one of 13 different and distinct genes. Because Applicants failed to elect what gene product was to be used in these 13 different assays, the response of 5/23/08 is non-responsive. Nevertheless, use of these 13 genes are recited in the alternative, and therefore, the rejection below anticipates these claims; thereby, providing further evidence for the lack of unity made of record and the lack of a "special" technical feature existing for the instant invention, because it does not define a contribution over the prior art. Thus, Applicants' arguments remain not persuasive, because the method of Group II involves a method of screening for unknown agents using detection of

distinct gene products not present in the Group I or III inventions. Thus, unity of invention is lacking under PCT Rule 13, for the reasons extensively made of record.

Claims 1-2 & 4 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/29/08 (even though the reply of 5/23/08 was non-responsive for further electing which specific gene of SEQ ID NOs: 1-13 was to be used in the assay of Group II).

This application contains claims 1-2 & 4 drawn to an invention nonelected with traverse in the reply filed on 1/29/08. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Benson et al (IDS Ref # DA).

Benson et al teach a method for identifying an agent (i.e., NGF) that increases synaptic growth or plasticity after contacting hippocampal neurons and PC-12 test cells with NGF, by detecting increased activation/expression of VGF protein precursor (e.g., pgs. 119-222, 224, 226 & Fig. 2). Increased activation of the VGF precursor nucleic acid sequence during axonal

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outgrowth and dendritic maturation is detected by the increased presence of “selectively and rapidly upregulated” translated product (e.g., pg. 221, bottom of 1<sup>st</sup> column & pg. 226) through increased binding to VGF antibodies when compared to the relative activation of the VGF protein precursor in untreated cells; thereby, indicating increased synaptic growth or plasticity, and anticipating claim 2.

### *Conclusion*

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Stucker, can be reached on (571) 272-0911. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert C. Hayes, Ph.D./  
Primary Examiner, Art Unit 1649  
September 9, 2008